EDA Assessment Report for Biological Medicinal Product

(Scientific Discussion)

Pelgraz

Date: March 2024

Unit: Technical Assessment Unit

Assessment report

Pelgraz

Administrative information:

Trade name of the medicinal product:	Pelgraz 6mg prefilled syringe
INN (or common name) of the active substance(s):	Pegfilgrastim 6mg/0.6ml Solution
Manufacturer of the finished product	Intas Pharmaceuticals Limited, Plot no 423 / P/A Sarkhej Bavla Highway Village Moraiya, Taluka Sanand, Ahmedabad – 382 213, Gujarat - INDIA.
Product License holder	Accord Healthcare Limited Sage House, 319 Pinner Road North Harrow, Middlesex HA1 4HF - United Kingdom
Applied Indication(s):	-Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).
Pharmaceutical form(s) and strength(s):	-solution for injection -strength: 6 mg
Route of administration	subcutaneous (s.c.) injection
Approved pack	Carton box containing 1 single-use pre-filled syringe of 0.6 ml solution with a permanently attached stainless steel injection needle, a needle safety guard and one alcohol swab.

List of abbreviations:

CHMP	Committee for Medicinal Products for Human Use
CI	Critical intermediate
DP	Drug product
DS	Drug substance
EC	European Commission
EMA	European medicines agency
mPEG-PAL	Methoxy Polyethylene Glycol Propionaldehyde
MVR	Method validation report
rHu G-CSF	recombinant human granulocyte

colony-stimulating factor

Dossier initial submission and evaluation process:

- The product was submitted for registration according to ministerial decree No. 343/ 2021 through normal track pathway.
- The dossier was initially received by the registration administration units on 14.4.2022 after providing all the required documents according to the "Checklist for documents of new biological products registration file".

1. **General introduction about the product including brief description of the AI, its mode of action and indications**:
   -Pelgraz (Pegylated Apo-Filgrastim) has been developed by Accord as a proposed biosimilar medicinal product to the reference product Neulasta® licensed by Amgen Inc. in different jurisdictions including EU, Canada and the USA.
   -On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the grant of a marketing authorisation for the medicinal product Pelgraz, intended to reduce the duration of neutropenia and the incidence of febrile neutropenia due to chemotherapy. Followed by this positive opinion, European Commission (EC) granted a marketing authorisation under Regulation (EC) No. 726/2004 of the European Parliament and of the Council for "Pelgraz - pegfilgrastim", a medicinal product for human use in pre-filled syringe presentation on 21 September 2018.
   -The input filgrastim, recombinant human granulocyte colony-stimulating factor (rHu G-CSF) is thus a Critical Intermediate (CI) used in the manufacture of Pegylated Apo-Filgrastim DS.

   -It is indicated for Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

2. **Quality aspects:**

- **Manufacturer(s):**

-both The active substance & finished product are manufactured at Intas pharmaceuticals limited Plot no 423 / P/A Sarkhej Bavla Highway Village Moraiya, Taluka Sanand, Ahmedabad – 382 213 Gujarat, INDIA.

- **Stability**
  - **Drug substance:**
    - **Approved Shelf Life:**

- Filgrastim Intermediates: 24 Months
- mPEG-PAL intermediate: 12 Months

- Active substance: 18 Months.

➢ **Approved storage Conditions:**

- Filgrastim Intermediates: 5 ± 3 °C
- mPEG-PAL intermediate: -20 ± 5 °C
- Active substance: 5 ± 3 °C

➢ **Drug product:**

➢ **approved Shelf Life:**

3 years

➢ **approved Storage Conditions:**

-Store in a refrigerator (2°C – 8°C).
-Pelgraz may be exposed to room temperature (not above 25°C ± 2°C) for a maximum single period of up to 72 hours. Pelgraz left at room temperature for more than 72 hours should be discarded.
-Do not freeze. Accidental exposure to freezing temperatures for a single period of less than 24 hours does not adversely affect the stability of Pelgraz.
-Keep the container in the outer carton in order to protect from light.

3. **Non-clinical and clinical aspects:**

General Conclusion and Recommendations if any:

Based on the review of CTD modules and other supplementary documents, the product is approved

For more information, please visit EMA published assessment report link:

https://www.ema.europa.eu/en/documents/assessment-report/pelgraz-epar-public-assessment-report_en.pdf